

U.S. PATENT OFFICE
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,515	06/12/2001	Billy W. Colston	IL-10715	5330

7590 04/30/2004

Alan H. Thompson
Assistant Laboratory Counsel
Lawrence Livermore National Laboratory
P.O. Box 808, L-703
Livermore, CA 94551

EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MY-CHAU T. TRAN

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 36-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of Appeal (PTO 800)

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/04 has been entered.

Status of Claims

2. Applicant's amendment filed 1/27/04 is acknowledged and entered. Claim 9 has been canceled. Claims 1, 8, and 41 have been amended. It is noted that in the claim listing applicant has indicated that claims 10-35 are withdrawn, which is an incorrect designation since claim 10-35 are cancelled.

3. Claims 10-35 are canceled by the amendment filed on 10/2/02.

4. Claims 1-8, and 36-43 are pending.

Withdrawn Rejections

5. In view of applicant's arguments and amendments of claims 1 and 41, the previous rejections under 35 USC 112, first paragraph (new matter) have been withdrawn.

6. In view of applicant's amendments of claims 1, 8, and 41 and cancellation of claim 9, the previous rejections under 35 USC 112, second paragraph, have been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-3, 5-6, 36 and 40 are rejected under 35 U.S.C. 102(b) as being anticipate by Pyle et al. (US Patent 5,821,066).

The instant claimed method of claim 1 recites a method for pathogen detection composed of sequential operations. The sequential method steps comprise: 1) containing optically encoded microbeads; 2) adding a sample and capture ligand to the contained microbeads; 3) placing the contained microbeads in a mixing holder for sufficient time for the targeted biological sample to adequately bind the microbeads; 4) adding fluorescent labeled antibodies for attachment to the microbead bound sample; 5) attaching the microbeads to a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto; 6) washing the substrate and attached microbeads; 7) inserting the substrate into an optical detection system for optically decoding the microbeads for identification and measurement of the target biological molecules. It is interpreted that steps 2-4 is the method of making the product use in step 1.

Pyle et al. disclose a method for the detection, identification and enumeration of a respiring target bacterium comprising the steps of: a) mixing immunomagnetic beads comprising

target bacteria; b) allowing said liquid sample to interact with the beads for up to an hour (step a) and b) would refer to step 2) and 3) of the instant claimed method, which would result in step 1) of the instant claimed method); c) placing the sample in a magnetic separator which causes the magnetic beads to which target bacteria have attached to separate from the liquid sample (referring to step 5); d) aspirating the liquid from the liquid sample, leaving the beads with bacteria attached; e) washing the beads with a solution which removes loosely bound bacteria and other particles from the liquid sample (referring to step 6 and claim 6); f) mixing beads with bacteria attached with a fluorochrome dye specific for the detection of respiring bacteria; g) treating bacteria on the beads with a fluorescent stain or a specific fluorescent conjugated antibody (either step f) or g) would refer to step 4)); h) mounting said sample for examination by epifluorescent microscopy, in which a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce; and i) quantifying said respiring target bacteria (step h) and i) would refer to step 7 of the presently claimed invention) (col. 12, lines 42-67 to col. 13, line 1). Further, following or simultaneously with incubation with the respiratory indicator, cells on the beads may be treated with a fluorescent stain or a specific fluorescent conjugated antibody (col. 18, lines 2-5). Therefore, either step f) and/or g) would precede step c). The sample is mounted by way of trapping the beads on a filter membrane and optically read (col. 14, lines 4-20). This would then provide the array pattern on such a membrane (referring to claim 5). The sample suspension containing the beads is allowed to interact for up to an hour, with gentle agitation (col. 17, lines 56-58) (referring to claim 3). Then the method of Pyle et al. anticipates the instant claimed sequential method.

The amendments of claim 1 wherein the deletion of "*the sequential operations*" would not overcome the method of Pyle et al. but rather the rejections under 35 USC 112, first paragraph (new matter). The additional steps of providing microbeads wherein the microbeads contained capture ligand and/or bioagent-specific antibodies are inherent steps of the method of Pyle et al. Therefore, the method of Pyle et al. anticipates the instant claimed method.

Response to Arguments

9. Applicant's arguments directed to the above rejection under 35 USC 102(b) as being anticipated by Pyle et al. (US Patent 5,821,066) for claims 1-3, 5-6, 36 and 40 was considered but they are not persuasive for the following reasons.

Applicant contends that the method of Pyle et al. does not anticipate the presently claimed method because (1) "[T]he Pyle et al. reference describes a rapid method for detection, identification and enumeration of specific respiring microorganisms" wherein the method includes the steps disclosed in the abstract; (2) "[T]he Pyle et al. Reference does not show the following steps of the claims presented for examination: "providing a multiplicity of optically encoded microbeads" or "providing a quantity of optically encoded microbeads" or "optically decoding said microbeads for detection and measurement of the targeted biological sample" or "optically decoding said microbeads for identification and measurement of the biological molecules attached to said microbeads"; and "[A]lso, the Pyle et al. Reference does not show the steps of the claims presented for examination: "adding fluorescent labeled antibodies to said contained microbeads and said sample for attachment to said bioagent-specific antibodies," or "attaching at least some of said microbeads to a disposable capture substrate containing an array of attachment sites for attaching said microbeads thereto," or "inserting said substrate into an

optical detection system”. Therefore the method of Pyle et al. does not anticipate the presently claimed method.

Applicant’s arguments are not convincing since the method of Pyle et al. does anticipate the presently claimed method. First, the reference of Pyle et al. discloses several different methods of detecting microorganism and one such method disclosed anticipate the presently claimed method (col. 12, lines 42-67 to col. 13, line 1). Additionally, it is noted that ‘*The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.*’ *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968))” (see MPEP 2123).

Second, the reference of Pyle et al. does disclose the steps of the presently claimed method. The method step of “providing a multiplicity of optically encoded microbeads” or “providing a quantity of optically encoded microbeads” is disclosed by Pyle et al. because the phrase ‘optically encoded microbeads’ is interpreted as microbead with “fluorescent labeled antibodies’ attached to it (i.e. the “optical encoding” of the microbead is due to the fluorescent labeled antibodies that is attach to the microbead, which is the “result” of the claimed method step of adding the fluorescent labeled antibodies to the microbead). The method of Pyle et al. discloses attaching a fluorescent conjugated antibody to the bead (i.e. bead with “fluorescent labeled antibodies’ attached to it) (col. 12, lines 62-63). Therefore the method Pyle et al. does disclosed the method step of “providing a multiplicity of optically encoded microbeads” or “providing a quantity of optically encoded microbeads”.

The method step of “optically decoding said microbeads for detection and measurement of the targeted biological sample” or “optically decoding said microbeads for identification and measurement of the biological molecules attached to said microbeads” is disclosed by the method of Pyle et al. because the method of Pyle et al. discloses examining the bead bound target by epifluorescent microscopy, in which a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce (i.e. optically decoding said microbeads for detection) **and** quantifying the target bacteria (i.e. measurement of the targeted biological sample) (col. 12, line 64 to col. 13, line 1). Thus method step of “optically decoding said microbeads for detection and measurement of the targeted biological sample” or “optically decoding said microbeads for identification and measurement of the biological molecules attached to said microbeads” is disclosed by the method of Pyle et al.

The method step of “adding fluorescent labeled antibodies to said contained microbeads and said sample for attachment to said bioagent-specific antibodies” is taught in the method of Pyle et al. (col. 12, lines 62-63) and the “attachment” of the fluorescent labeled antibodies to the bioagent-specific antibodies is interpreted as an indirect attachment (i.e. the microbead is attached to bioagent-specific antibodies, the sample is attached to the bioagent-specific antibodies, and the fluorescent labeled antibodies is attached to the sample). The “attachment of the fluorescent labeled antibodies to the bioagent-specific antibodies” of Pyle et al. is also an indirect attachment (i.e. the bead is attached to the antibody (bioagent-specific antibodies), the target bacteria (sample) is attached to the antibody, and the fluorochrome labeled antibody (fluorescent labeled antibodies) is attached to the target bacteria). Thus method step of “adding fluorescent labeled antibodies to said contained microbeads and said sample for attachment to

said bioagent-specific antibodies” is taught in the method of Pyle et al. Furthermore, the specification pg. 11, paragraph [0038] and figure 6 disclose and indirect attachment of the fluorescent labeled antibodies to the bioagent-specific antibodies.

The method step of “attaching at least some of said microbeads to a disposable capture substrate containing an array of attachment sites for attaching said microbeads” is taught in the method of Pyle et al. The method of Pyle et al. discloses two different ways of “attaching” the beads to the substrate. One is by a magnetic separator to attach the magnetic bead (charged microbeads as claimed in claim 36) to the tube (substrate) (fig. 2, col. 12, lines 51-53) and the second is by trapping the beads on a filter membrane (col. 14, lines 4-20). Therefore, the method of Pyle et al. does teaches the method step of “attaching at least some of said microbeads to a disposable capture substrate containing an array of attachment sites for attaching said microbeads”.

The method step of “inserting said substrate into an optical detection system” is taught in the method of Pyle et al. The method of Pyle et al. uses an epifluorescent microscope (optical detection system) so that a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce of the sample (col. 12, line 64 to col. 13, line 1; col. 14, lines 4-20) and the sample are mounted (i.e. the tube or filter membrane are “place” into the epifluorescent microscope). Thus the method of Pyle et al. does teach the method step of “inserting said substrate into an optical detection system”.

Therefore, the reference of Pyle et al. does disclose the steps of the presently claimed method and the method of Pyle et al. does anticipate the presently claimed method.

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pyle et al. (US Patent 5,821,066) and Nazareth et al. (US Patent 6,319,676 B1).

The instant claimed method of claim 1 recites a method for pathogen detection composed of sequential operations. The sequential method steps comprise: 1) containing a quantity of microbeads; 2) adding a sample and capture ligand to the contained microbeads; 3) adding fluorescent labeled antibodies for attachment to the microbead bound sample; 4) providing a disposable capture substrate containing an array of attachment sites for attaching the microbeads thereto; 5) inserting the disposable capture substrate containing the array of attachment sites into the contained microbeads for capturing the microbeads; and 6) inserting the substrate into an optical detection system for optically decoding the microbeads for identification and measurement of the target biological molecules. Additionally including the contained quantity of microbeads to be optically encoded (Claim 42). It is interpreted that steps 1-3 is the method of making the product use in the claimed method step 42. Thus, claim 43 is a duplicate of step 6 in claim 41.

Pyle et al. disclose a method for the detection, identification and enumeration of a respiring target bacterium comprising the steps of: a) mixing immunomagnetic beads comprising an antibody which specifically binds to a target bacteria with a liquid sample comprising said target bacteria; b) allowing said liquid sample to interact with the beads for up to an hour (step a)

of the instant claimed method); c) placing the sample in a magnetic separator which causes the magnetic beads to which target bacteria have attached to separate from the liquid sample (referring to step 4); d) aspirating the liquid from the liquid sample, leaving the beads with bacteria attached; e) washing the beads with a solution which removes loosely bound bacteria and other particles from the liquid sample; f) mixing beads with bacteria attached with a fluorochrome dye specific for the detection of respiring bacteria; g) treating bacteria on the beads with a fluorescent stain or a specific fluorescent conjugated antibody (either step f) or g) would refer to step 3)); h) mounting said sample for examination by epifluorescent microscopy, in which a suitable light filter system is used to excite the fluorochrome dye and fluorochrome labeled antibody to fluoresce; and i) quantifying said respiring target bacteria (step h) and i) would refer to step 6 of the presently claimed invention) (col. 12, lines 42-67 to col. 13, line 1). Further, following or simultaneously with incubation with the respiratory indicator, cells on the beads may be treated with a fluorescent stain or a specific fluorescent conjugated antibody (col. 18, lines 2-5). Therefore, either step f) and/or g) would precede step c).

The amendments of claim 41 wherein the deletion of "*the sequential operations*" would not overcome the method of Pyle et al. but rather the rejections under 35 USC 112, first paragraph (new matter). The additional steps of providing microbeads wherein the microbeads contained capture ligand and/or bioagent-specific antibodies are inherent steps of the method of Pyle et al.

The method of Pyle et al. does not expressly disclose the method step of inserting the disposable capture substrate into the contained microbeads for capturing the microbeads.

Nazareth et al. disclosed a device and method for detecting the presence of analyte in the body fluids (col. 1, lines 44-46). The assay method comprise of a dipstick for dipping in a container of test solution (col. 8, lines 28-30) and a capture site wherein a complex is form comprising immobilized capture agent-capturable conjugate-analyte-labeled binding member (col. 8, lines 45-47).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the method step of inserting the disposable capture substrate into the contained microbeads for capturing the microbeads as taught by Nazareth et al. in the method of Pyle et al. One of ordinary skill in the art would have been motivated to include the method step of inserting the disposable capture substrate into the contained microbeads for capturing the microbeads in the method of Pyle et al. for the advantage of providing an assay system which involves a minimal number of procedural steps, and reproducibility yields reliable results even when used by untrained persons (Nazareth: col. 1, lines 48-50).

Response to Arguments

12. Applicant's argument(s) directed to the above rejection under 35 USC 103(a) as being unpatentable over Pyle et al. (US Patent 5,821,066) and Nazareth et al. (US Patent 6,319,676 B1) for claims 41-43 was considered but they are not persuasive for the following reasons.

Applicant alleges that the combination of the method of Pyle et al. and the method of Nazareth et al. is non-obvious over the presently claimed method because the method of Pyle et al. does not disclosed the method steps of the presently claimed method and the method of Nazareth et al. does not cure the deficiencies. These steps are: “[p]roviding a quantity of optically encoded microbeads,” or “adding fluorescent labeled antibodies for attachment to said

bioagent specific antibodies” or “providing a disposable capture substrate containing an array of attachment sites for attaching said microbeads' thereto,” or “inserting said disposable capture substrate containing an array of attachment sites into said contained microbeads for capturing said microbeads,” or “inserting said disposable capture substrate into a detection system,” or “optically decoding said microbeads for identification and measurement of the biological molecules attached to said microbeads.”

Applicant's arguments are not convincing since the combination of the method of Pyle et al. and the method of Nazareth et al. is obvious over the presently claimed method. The claimed method steps are teaches by the method of Pyle et al. as shown above in the arguments for rejection under 35 U.S.C. 102(b). Therefore the combination of the method of Pyle et al. and the method of Nazareth et al. is obvious over the presently claimed method.

New Rejections

Claim Rejections - 35 USC § 112

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-8, and 36-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 1 and 7 recite the method step of containing the microbeads. However, the type of “containing” (i.e. for performing or for storing) claimed in claim 1 and 7

placing the microbead in a container in order to perform the assay) where as in claim 7 it is for storing (i.e. placing the microbead in a container for storage). Furthermore, the specification does not provide support for performing the assay in a "disposable bead pack". Therefore, the containing step is indefinite with regard to claims 1 and 7.

b. Claim 1 lacks clear antecedent basis for the phrase "contained microbeads" in line 7. The containing step of claim 1 referred to an optically encoded microbeads.

c. Claim 2 and claim 7 lack clear antecedent basis for the phrase "containing said microbeads" in line 2. The containing step of claim 1 referred to an optically encoded microbeads.

d. Claim 8 recites the method of claim 1 additionally includes the step of an assay. This is confusing because claim 1 is claiming an "assay" method. Thus, it is unclear as to applicant's intent as to the additional assay step.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Seul et al. (US Patent 6,387,707 B1).

Seul et al. disclose several different methods for detection and measurement of a sample (Abstract). One method comprises forming a bead capture probe target complexes in well, and depositing the bead complexes onto electrode (substrate), and optically detected and measure (col. 31, lines 6-35; fig. 10). The beads included color beads (col. 25, lines 6-23). Thus the method of Seul et al. anticipates the presently claimed method.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall (US Patent 5,236,826) and Okusa et al. (US Patent 4,952,520).

Marshall teaches a method for the detection of an analyte (col. 3, lines 19-45; col. 7, lines 23-45). The method steps are mixing the analyte with the particle-bound binding component and allowing them to react, adding a second binding component labeled with a signal-generating material to form an immunocomplex of particle-bound binding component:analyte:labeled binding component, separating the immunocomplex from the reaction mixture by a filtration procedure in which the filter material (substrate) retained the particle because of its size in the filter interstices (col. 7, lines 30-34), the complex is then washed to remove unbound labeled binding component, and the reaction area is read to measure the amount of signal present. The analyte includes parasitic antigen (col. 6, lines 65-68). The particle includes bead (col. 4, lines 12-20). The label must be capable of emitting a signal such as fluorescent (col. 7, lines 7-22). Where enzymes labeling is use to produce a readable signal by a photometer with monochromatic light, by scanning the spectrum the instrument could distinguish the different wavelength signal (col. 8, lines 62-68), which would then provide the array pattern.

Marshall does not expressly disclose that the filter material (substrate) is on a dipstick.

Okusa et al. teaches an immunoassay in which the colored latex particle are capture on a membrane that is attached to a test device (dipstick) (col. 2, lines 11-17; col. 4, lines 9-23; fig. 1 and 3).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the membrane in Marshall with the membrane attached to a dipstick as taught by Okusa et al. in the method of Marshall. One of ordinary skill in the art would have been motivated to substitute the membrane in Marshall with the membrane attached to a dipstick for the advantage of providing a compact bioanalytical filtering system to be use in an environment other than the laboratory since both Marshall and Okusa et al. teach the method of capturing the analyte bound particle by filtration (Marshall: col. 7, lines 30-34; Okusa: col. 2, lines 11-17). Furthermore, one of ordinary skill in the art would have reasonably expectation of success in the combination of Marshall and Okusa et al. because the taught method would need no modification other than attaching the membrane to device that do not materially affect the assay method steps that form an immunocomplex of particle-bound binding component:analyte:labeled binding component that are capture on the membrane.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
April 23, 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER